SP-1

Spirometer

Welch Allyn™
Schiller®

SP-1 User Guide

Article Number 2.510271a

Welch Allyn® Schiller®

Welch Allyn Inc.
7420 Carroll Road
San Diego, CA 92121

Phone: (800) 854-2904
Fax: (858) 621-6611

www.welchallyn.com

United Kingdom:

Welch Allyn UK Ltd
Cubblington Road
Aston Abbotts HP22 4ND
United Kingdom

Tel: 01296-682-140
Fax: 01296-682-104

Canada:

Welch Allyn Canada Ltd
160 Matheson Blvd. East, Unit #2
Mississauga, Ontario L4Z 1V4
Canada

Tel: (800) 561-8797
Fax: (905) 890-0008

DECLARATION OF CONFORMITY

Spirometer: **SP-1**

Serial numbers starting with: 540.

Year of manufacture: 1995 Onwards

We, the undersigned, hereby declare that the medical device (class IIa) specified above conforms with the essential requirement listed in Annex 1 of EC Directive 93/42/EEC.

This declaration is supported by:

Certificate of approval No:	11425-01	ISO 9001 (Rev.1994) EN 46001 by SQS
	45112-60-00	ISO 9001/08.94, EN 46001 / 12.93 by DEKRA
and	45112-16-00	Annex II, Section 3 of the Directive 93/42/EEC (30.04.1995)

CE 0124

Baar (Switzerland) 03.07.1996

M. Spreng

Martin Spreng
Research & Development Manager

Markus Bütler
Quality Assurance Manager

Disclaimer

The Information in this guide has been carefully checked for reliability; however no guarantee is given as to the correctness of the contents and WELCH ALLYN SCHILLER makes no representations or warranties regarding the contents of this manual. We reserve the right to revise this document and make changes in the specification of the product described within at any time without obligation to notify any person of such revision or change.

Trademarks

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Copyright Notice

Terms of Warranty

WELCH ALLYN SCHILLER warrants the SP-1 Spirometer, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer`s specifications for the period of three (3) years from the date of purchase from Welch Allyn or it`s authorized distributors or agents. Accessory items such as electrodes, batteries and cables are limited to a warranty of 90 days from the date of purchase from Welch Allyn or its authorized distributors or agents. Welch Allyn will repair or replace any components found to be defective or at variance from manufacturer`s specifications within this time at no cost to the customer. It shall be the purchasers responsibility to return the instrument to Welch Allyn or an authorized distributer, agent or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modifications or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer`s recommendations or if repaired by other than Welch Ally or an authorized agent. Purchase date determines warranty requirements. No other express warranty is given.

Schiller®

PHYSICIAN'S RESPONSIBILITY

THE SP-1 SPIROMETER IS PROVIDED FOR THE EXCLUSIVE USE OF QUALIFIED PHYSICIANS OR PERSONNEL UNDER THEIR DIRECT SUPERVISION. THE NUMERICAL AND GRAPHICAL RESULTS FROM A RECORDING MUST BE EXAMINED WITH RESPECT TO THE PATIENTS OVERALL CLINICAL CONDITION. THE RECORDING PREPARATION QUALITY AND THE GENERAL RECORDED DATA QUALITY, WHICH COULD EFFECT THE REPORT DATA ACCURACY, MUST ALSO BE TAKEN INTO ACCOUNT.

IT IS THE PHYSICIANS RESPONSIBILITY TO MAKE THE DIAGNOSIS OR TO OBTAIN EXPERT OPINION ON THE RESULTS, AND TO INSTITUTE CORRECT TREATMENT IF INDICATED.

FEDERAL LAW IN THE USA RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

Safety Notices

THIS UNIT IS BF CLASSIFIED ACCORDING TO IEC 601-1.

TO PREVENT ELECTRIC SHOCK DO NOT DISASSEMBLE THE UNIT. NO SERVICEABLE PARTS INSIDE. REFER SERVICING TO QUALIFIED PERSONNEL ONLY.

DO NOT USE THIS UNIT IN AREAS WHERE THERE IS ANY DANGER OF EXPLOSION OR THE PRESENCE OF FLAMMABLE GASES SUCH AS ANAESTHETIC AGENTS.

THIS PRODUCT IS NOT DESIGNED FOR STERILE USE.

THIS PRODUCT IS NOT DESIGNED FOR OUTDOOR USE.

SWITCH THE UNIT OFF BEFORE CLEANING AND DISCONNECT FROM THE MAINS.

DO NOT, UNDER ANY CIRCUMSTANCES, IMMERSE THE UNIT OR CABLE ASSEMBLIES IN LIQUID.

THE DEVICE MUST ONLY BE OPERATED USING BATTERY POWER IF THE EARTH CONNECTION IS SUSPECT OR IF THE MAINS LEAD IS DAMAGED OR SUSPECTED OF BEING DAMAGED.

DO NOT USE HIGH TEMPERATURE STERILISATION PROCESSES (SUCH AS AUTOCLAVING). DO NOT USE E-BEAM OR GAMMA RADIATION STERILISATION.

DO NOT USE SOLVENT CLEANERS

USE ONLY ACCESSORIES AND OTHER PARTS RECOMMENDED OR SUPPLIED BY WELCH ALLYN SCHILLER. USE OF OTHER THAN RECOMMENDED OR SUPPLIED PARTS MAY RESULT IN INJURY INACCURATE INFORMATION AND/ OR DAMAGE TO THE UNIT.

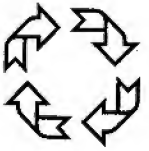
THE SP-1 COMPLIES WITH EMC REGULATIONS FOR MEDICAL PRODUCTS WHICH AFFORDS PROTECTION AGAINST EMISSIONS AND ELECTRICAL INTERFERENCE. HOWEVER SPECIAL CARE MUST BE EXERCISED WHEN THE UNIT IS USED WITH HIGH FREQUENCY EQUIPMENT.

SP-1 User`s Guide

This User`s Guide gives instructions on how to operate the unit and provides an overview of all the basic functions in an easy and simple to use format. The procedures are presented in a logical, step-by step way to enable the user to quickly and easily familiarise themselves with unit operation. Detailed medical information is excluded from this guide except where necessary to operate the unit or understand the results.

This equipment has been tested and found to comply with the limits for a class A digital device, pursuant to both Part 15 of the FCC (Federal Communications Commision) Rules and the radio interference regulations of the Canadian Department of Communications. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with this instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Disposal Instructions and Battery Care



- DO NOT DISPOSE OF THE BATTERY BY FIRE OR INCINERATOR - DANGER OF EXPLOSION
- DO NOT ATTEMPT TO RECHARGE THE BATTERY - DANGER OF EXPLOSION
- DO NOT OPEN THE BATTERY CASING - DANGER OF ACID BURN

Only dispose of the battery in official recycling centres or municipally approved areas. Alternatively used batteries can be returned to Schiller AG for disposal.

Unit Disposal Instructions

Units no longer required can be returned to Schiller AG for disposal. Alternatively dispose of the unit in municipally approved recycling centres.

Power Supply

The mains connection is on the rear of the unit.

The power supply voltage is set by the factory for100-115V(nom. 110V) or 220-240V (nom. 230V) working. The setting is indicated by the indented metal strip on the fuse panel. Contact your dealer if the voltage needs to be changed.

The mains indicator lamp on the keyboard is always lit when the unit is connected to the mains supply. The unit can either be operated from the mains supply or from the built-in rechargeable battery. The power source is indicted on the top line of the LCD.

Changing a Mains Fuse

If it is necessary to change a fuse, always replace with the correct rating i.e 2x200mAT for 230V, or 2x315mAT for 110V .

To change a fuse press the two retaining lugs on side of the fuse panel (situated below the mains connector on the back panel. Remove the fuse panel and replace the fuse(s). Click back the fuse panel.

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CE 0124

93/42/EEC Medical Devices:
0124 `Notified Body` DEKRA AG

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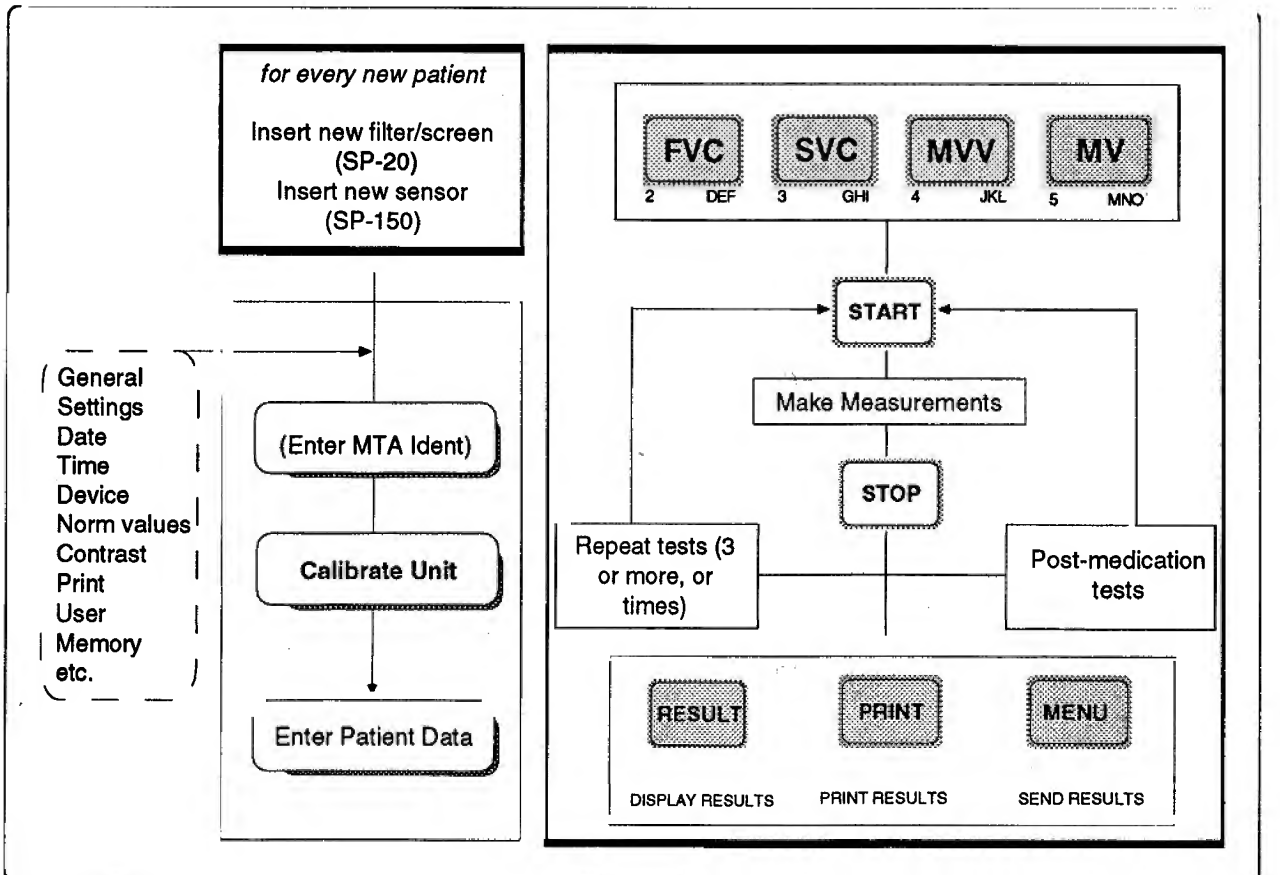
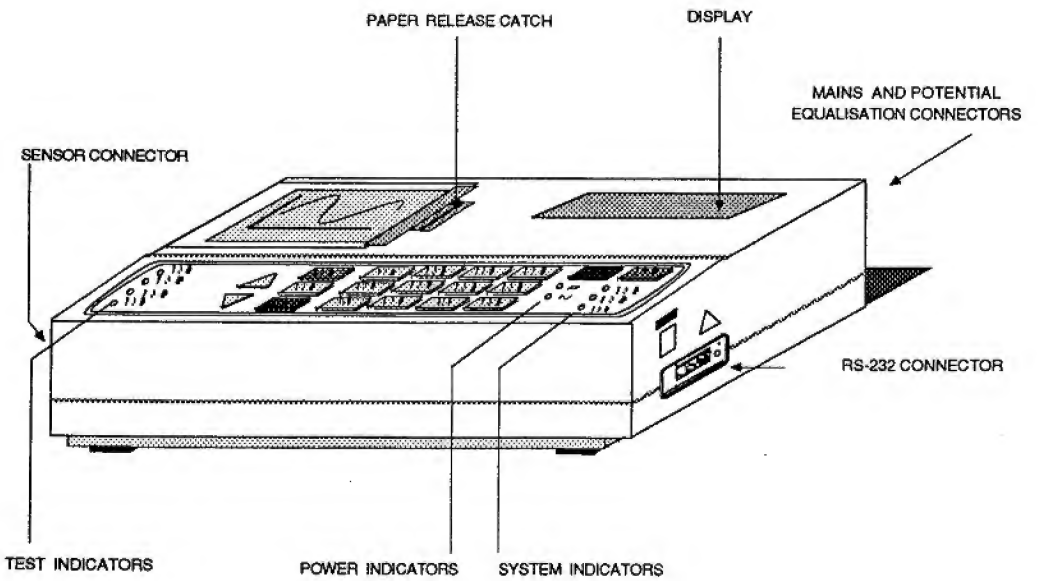

for every new patient
Insert new filter/screen (SP-20)
Insert new sensor (SP-150)
General Settings
Date
Time
Device
Norm values
Contrast
Print
User
Memory
etc.
(Enter MTA Ident)
Calibrate Unit
Enter Patient Data
FVC
2 DEF
SVC
3 GHI
MVV
4 JKL
MV
5 MNO
START
Make Measurements
STOP
Repeat tests (3 or more, or times)
Post-medication tests
RESULT
PRINT
MENU
DISPLAY RESULTS
PRINT RESULTS
SEND RESULTS

Procedure Overview

1	Switch ON
2	Make Settings preference if required (remembered when unit switched off)
3	Insert new screen/filter or sensor
4	Calibrate Unit
5	Enter patient data
6	Select test
7	Press START
8	Patient Makes test
9	Press STOP
10	Repeat as many times as required (Best, or best two + last printed)
11	Display result
12	Print Result
	Send result if required


PAPER RELEASE CATCH
DISPLAY
MAINS AND POTENTIAL EQUALISATION CONNECTORS
SENSOR CONNECTOR
RS-232 CONNECTOR
TEST INDICATORS
POWER INDICATORS
SYSTEM INDICATORS

The SCHILLER SP-1 is a stand-alone pulmonary function testing unit that features four modes for the measurement of inspiratory and expiratory values. The unit incorporates a liquid crystal display to instantly show the test results. An integral high quality thermal printer provides clear and comprehensive result analysis in a number of different formats and an RS-232 interface is provided for transmission of test results to a PC. All tests and settings are initiated via an easy to use keypad with dedicated test keys. Test indicators show the current test being carried out and function LEDs provide visual indication for functions such as power, sensor disconnected, paper tray empty and paper jam. Measurements are made with a lightweight and hygienic open pneumotacho sensor. Two sensors are available. The SP-20 open pneumotacho sensor incorporates a disposable filter and is easily dismantled for cleaning and sterilisation. The SP-150 sensor has a disposable, single patient sensor/ filter assembly eliminating the need to clean the sensor after each use. The SP-1 has the following features:

- Direct function keys for measuring the following:
  - **FVC Forced Vital Capacity**
  - **SVC Slow Vital Capacity**
  - **MVV Maximum Voluntary Ventilation**
  - **MV Expired or Minute Ventilation**
- Low weight and compact dimensions
- Built-in rechargeable battery for mains-independent use
- Selectable printing formats with integrated quality thermal printer
- Patient memory for up to approximately 100 single measurements (option)
- Choice of 6 languages for display and printing

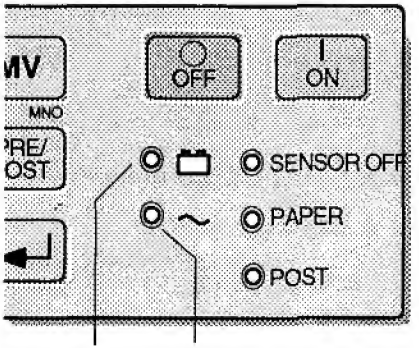
As with all medical units, the following general rules are to be noted:

- The unit should not be stored or operated in a wet, humid or dusty environment.
- The unit may not come into contact with acidic steams or liquids.
- The unit should not be set up near radiology or diathermic systems, or near large transformers or electrical motors. Ensure that a minimum distance of 1 meter between the unit and the mains supply is maintained

Potential Equalisation

In certain circumstances interference can be caused by external electrical equipment or radio equipment. Connect the earth potential equalisation connection at the back of the SP-1 to the hospital common ground or, if a common ground is not present, to a metal framework e.g. the bed frame. Note that all other electrical equipment in close proximity should also be connected to the same common ground. The part number of the potential equalisation cable is 2. 310 005.

The unit can be operated from the mains or from the built-in rechargeable battery. The mains connection is on the rear of the unit. The mains indicator lamp is always lit when the unit is connected to the mains supply. A battery indicator lamp confirms battery operation. When the battery capacity is limited, the indicator flashes. To recharge the battery, connect the apparatus to the mains supply by means of the supplied power cable. A totally discharged battery needs less than 15 hours to be fully recharged (60% in less than 3 hours).



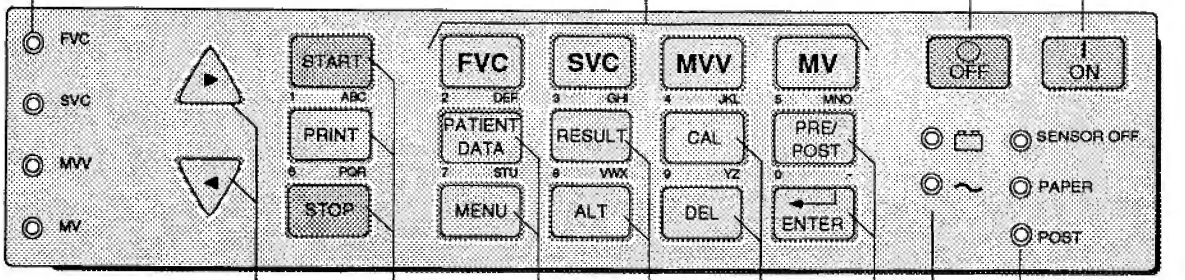
Lit when operating from the internal battery. Flashes when battery has limited capacity

Lit when mains supply connected

A fully charged battery lasts approximately 2 hours of normal use. The unit can remain connected to the mains supply without any danger of damage to either the battery or the unit.

Switching On and Off

The SP-1 is switched on and off with the ON and OFF keys.



Indicates the test currently being carried out

Enter Lung Function Test Menu as designated (Commence each measurement with START; end each measurement with STOP)

Switch unit off

Switch unit on

Move Display Cursor

Start Measurement
Print Measurement
Stop Measurement or Stop Printout

Enter **Patient Data**
Display **Menu** options for the indirect functions or Escape

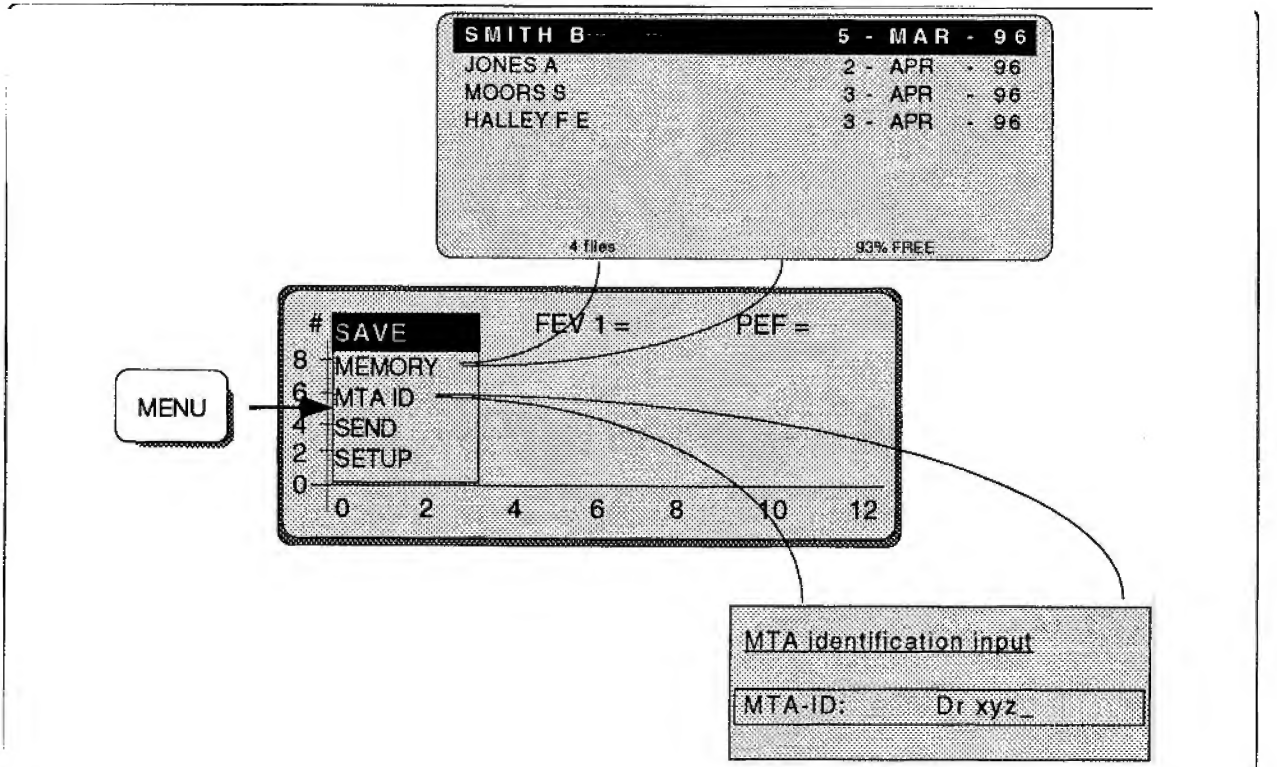
Display **Result** of the test
Change key to second function

Calibibrate unit
Delete a character/delete last measurment

Pre and Post medication test
Enter menu option displayed or confirm entry

Battery Operation / Mains Connected

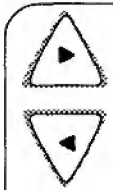
Sensor not connected
Paper jam or no paper in paper tray
Post test being carried out



Note that the Save and the Memory menu items only appear when the memory option is installed

Main Menu

Save	This option only appears when the memory option is installed. Select this option to save the current measurement in the memory.
Memory	This option only appears when the memory option is installed. Select the memory menu item to: . Print a stored recording . Delete a recording . Send a recording
MTA Ident	Enter the name of the person carrying out the test. The MTA name (medical technical Assistant) is given on printouts. The users name entered here, is remembered when the unit is switched off; it only needs updating when a new user takes over.
Send	Current recording is sent over the RS-232 interface (for example to the SEMA PC storage program). Note that the RS-232 protocol settings must be defined in the setup menu before transmission.
Setup	See System Setup Menu following



When a menu is displayed use these keys to move the cursor UP / DOWN. When an enter field is displayed e.g. MTA Ident, use these keys to move the cursor LEFT / RIGHT

When a menu is displayed - press this key to select highlighted menu option. When an enter field is displayed e.g. MTA Ident, use this key to confirm entry and to exit field

Use this key to display the main menu as above. When an enter field is displayed, this key is used the same as the ENTER key to confirm entry and to exit field

Setting the Contrast

Change the contrast of the screen to your preference as follows:

Press the ALT key and the MENU key together then change the contrast with the cursor keys UP and DOWN

Entering data in a field

Printed below certain keys on the keyboard are letters. In a data field (e.g. MTA Ident) press the key once to enter the first character, twice to enter the second character, and three times to enter the third character.

The character is displayed on the screen as entered. Press the right cursor key to confirm the entry and move to the next character position.

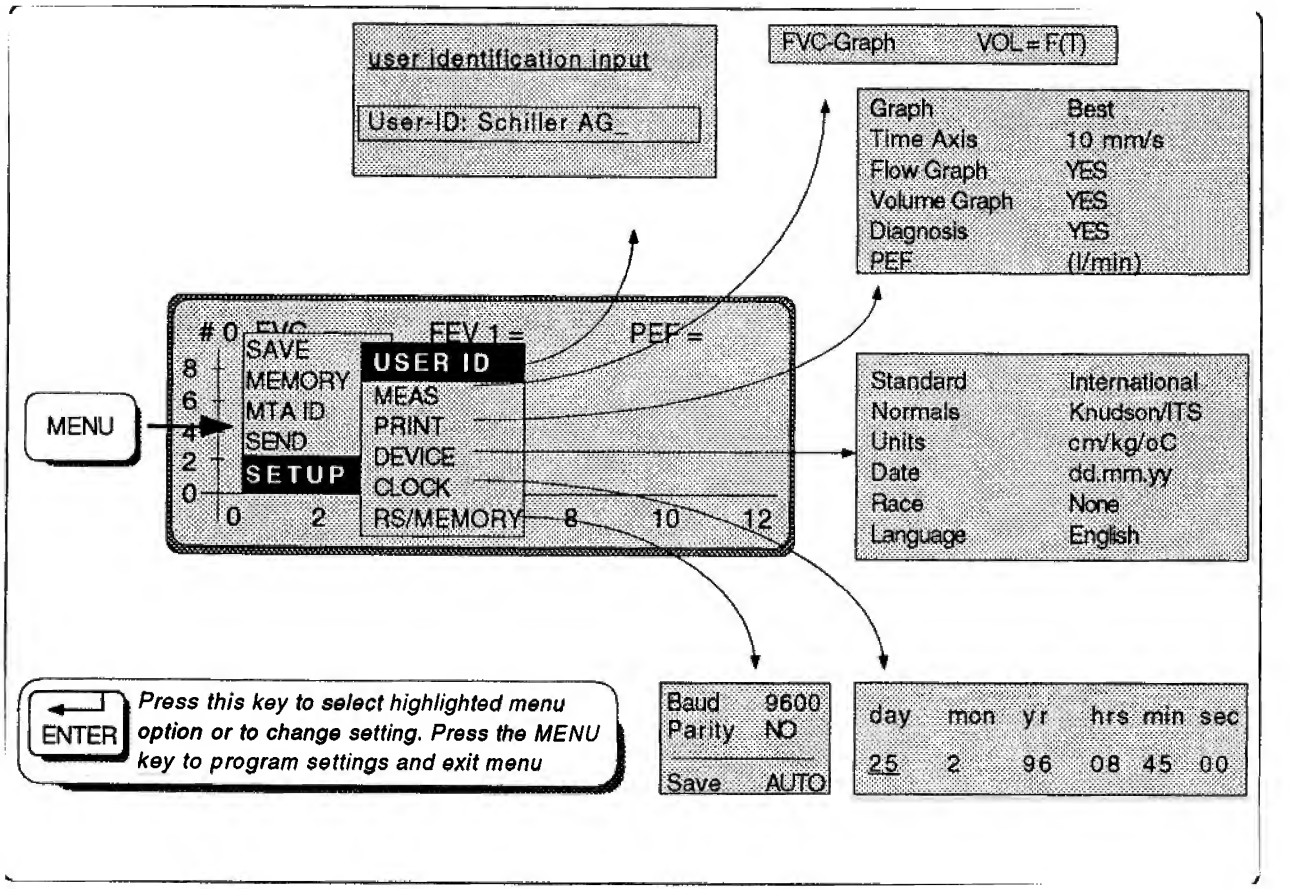
Use the left and right cursor keys at any time to select a position to change that character.

Press the ENTER key or the MENU key to confirm entry and exit the field.

When an entry field requires a numerical input e.g. date of birth, the number keys are automatically selected. When an entry field requires a letter input e.g. patient name, the letter keys are automatically selected. If a numerical input is required for example in the patient name, or conversely a letter input required in the date of birth, pressing the ALT key before the character/number key enables this. Therefore when entering data:

ALT + key = number input in character field

ALT + key = character input in number field

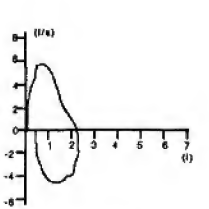

user identification input
User-ID: Schiller AG_
FVC-Graph VOL = F(T)
Graph Best
Time Axis 10 mm/s
Flow Graph YES
Volume Graph YES
Diagnosis YES
PEF (l/min)
0
FEV 1 =
PEF =
MENU
SAVE
MEMORY
MTA ID
SEND
SETUP
USER ID
MEAS
PRINT
DEVICE
CLOCK
RS/MEMORY
8
6
4
2
0
0
2
8
10
12
Standard International
Normals Knudson/ITS
Units cm/kg/oC
Date dd.mm.yy
Race None
Language English
ENTER
Press this key to select highlighted menu option or to change setting. Press the MENU key to program settings and exit menu
Baud 9600
Parity NO
Save AUTO
day mon yr hrs min sec
25 2 96 08 45 00

This menu option defines all the general settings. All entries remain stored (even when the unit is switched off) until overwritten. The settings are as follows:

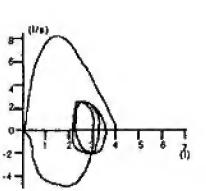
User Ident Use this to enter the name of the consultant or department that operates the unit.

Measurement This is how the FVC graph is displayed and printed. With the ENTER key toggle the options to set a flow display of one of the following:

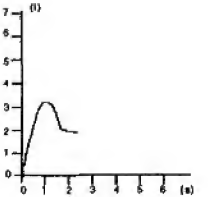
- Flow = f(vol)
- Flow = loop
- Vol =f(t)



Flow = f(vol)



Flow = Loop



Vol = f(t)

Print

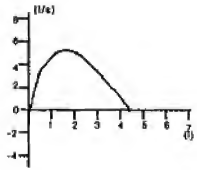
This defines the format and content of the printout when the PRINT key is pressed. The settings are as follows:

Graph Select ALL or BEST (measurements)

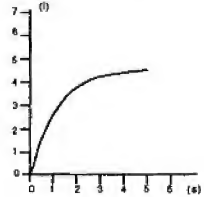
Time Axis This defines the time axis of the graph - set to 10mm/s or 20mm/s

Flow Graph Set to ON or OFF - graph printed or not printed

Vol Graph Print the volume graph - select YES or NO



Flow Graph



Volume Graph

Diagnosis Diagnosis printed or not printed -select YES or NO

PEF Peak Expiratory flow calculation - select litres/min or litres/second

Device	STANDARD	Set to 'International' for all countries outside the USA and Canada or to 'American' for USA and Canada
	NORMALS	The diagnosis is based on the standard defined here. The Normal value standards are given at the end of this section- 'Diagnosis and Norm Value Tables'
	UNITS	Set to : cm / kg /°C, cm / kg /°F, inch / lb. /°F
	DATE	Set the order of the date to month - day - year, day - month - year or year-month-day
	RACE	set to: NONE (no race); recommended for Europe, W/B (White/ Black) for all countries outside the USA and Canada C/H/B/A (Caucasian / Hispanic / Black / Asian) for USA and Canada *The standards and Norm Values are detailed at the end of this section (Diagnosis and Norm Values). The individual setting for race, and the effect of race on results is detailed in the Patient data (see following page)*
	LANGUAGE	This defines the language on the printout and menu structure. Set to English, German, French, Italian, Spanish, or Portuguese

Clock Set the time and date

RS/Memory The Baud rate (300 to 38400) and parity setting (No/odd/even) for sending over the RS interface must be set to the same as the receiving unit.

The save options are MAN (manual) or AUTO (automatic). When the save option is set to AUTO, all measurements are automatically saved when completed (only when the memory option is installed).

Press the MENU key to confirm all settings and exit the setup menu. The following table shows typical setup combinations.

Norm Values (Normals)	Spirometry Standard	Race	Units
ECCS / QUANJER	International	(W/B) or NONE	cm/kg/C
BERGLUND / QUANJER			
FINNISH / QUANJER			
INDIAN			
ÖSTERREICH			
KNUDSON / ITS	American	(C/H/B/A) or NONE	inch/lb/F
KNUDSON76 / ITS			
CRAPO / ITS			
MORRIS / ITS			
POLGAR / ITS			
COMPOSITE			

Each printout is complete with the name and other information concerning the patient. Before beginning a recording, the patient data should be entered. The following parameters have to be entered:

Pat-Name: Patient name

Pat-No: Patient number

Age: Enter age of patient in whole years

Sex: Select "M" (male) or "F" (female).

Height: Height in centimetres (or inches (scaled to 1/10 inch), depending on unit setup).

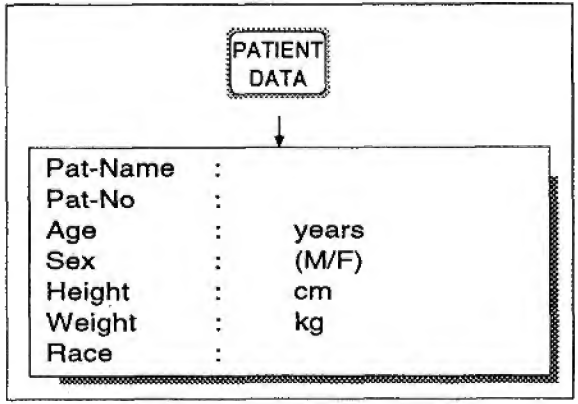
Weight: Weight in kilogrammes (or pounds, depending on unit setup).

Race: Enter patients race:

W/B: "W" for White, "B" for Black

C/H/B/A: "C" for Caucasian, "H" for Hispanic, "B" for Black or "A" for Asian

If this position does not appear, "NONE" was selected in the device setup. (menu option <SETUP> <DEVICE> <RACE> see previous page.



Wrongly typed characters can be deleted by pressing the **DEL** (delete) key.

Race Influences on Norm Values

According to the setting of the patients race the predicted values will differ. The differences are (according to ITS recommendations) as follows:

- When in the "Settings" menu **NONE** was set:

  All values are calculated according to the given formulas.

- When in the "Settings" menu **(W/B)** was set:

  W (White): values are calculated according to the given formulas (= 100%)

  B (Black): 85% of the given formulas

- When in the "Settings" menu **(C/H/B/A)** was set:

  C (Caucasian): values are calculated according to the given formulas (= 100%)

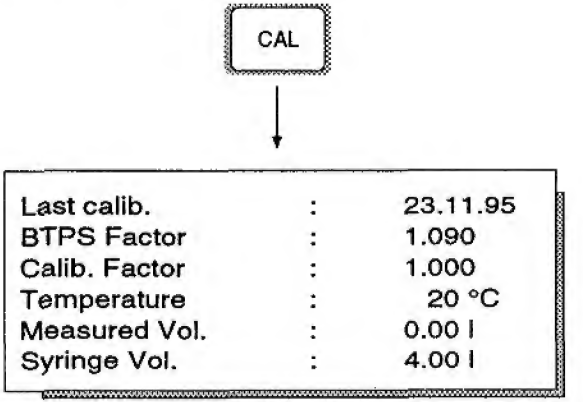
  H (Hispanic): values are calculated according to the given formulas (= 100%)

  B (Black): 85% of the given formulas

  A (Asian): 85% of the given formulas

  The 85% race compensation is calculated only when the following normal values are selected: COMPOSITE; KNUDSON; CRAPO; MORRIS; POLGAR

To calibrate, proceed as follows:



IMPORTANT

THE UNIT MUST BE CALIBRATED WITH THE FIRST PULMONARY FUNCTION TEST OF THE DAY, AFTER EVERY SIGNIFICANT TEMPERATURE CHANGE OR AFTER CHANGING THE SENSOR.

Last Calibration	date of last calibration
BTPS	Factor calculated BTPS (=> **B**ody **T**emperature, Ambient **P**ressure, **S**aturated with water vapour) value. This value compensates for the difference in inhaled and exhaled humidity. The unit is set for measuring exhaled volume (100% humidity, Temp 36.8°), and so when inhaled volume is measured this factor is applied. The SP-1 uses ambient temperature to calculate the BTPS factor. This is sufficient for accurate FIVC calculation. The formula used is as follow:
Calibration Factor	calculated value between measured and effective calibration air volume
Temperature	ambient temperature in °C (or °F) dependent on device setting
Measured Volume	air volume measured by the system from the calibration pump
Syringe Volume	entered air volume depending on the size of the calibration pump and times the air was pumped through the sensor; e.g. pumping 2 litres 3 times amounts to 6 litres (the recommended volume with a 2 litre pump is 4 litres; with 3 litre pump, 6 litres)

$$BTPS = 0.033 + \frac{273.15 + 36.8}{273.15 + Tu}$$

Tu is ambient temperature degrees centigrade
0.033 is equivialent to 760mmHg at 22 degrees C
273.15 is degrees absolute

Calibration Procedure

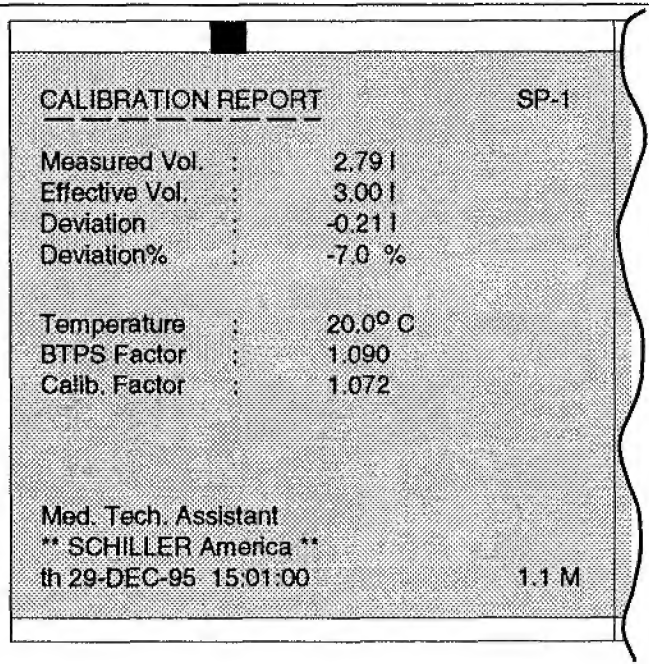
To calibrate the unit proceed as follows:

- Connect the calibration pump to the sensor. Ensure that there are no air leaks
- Press the CAL key - the menu is displayed as shown on the previous page
- The cursor is positioned at temperature. Enter the ambient temperature
- Press ENTER when the correct temperature entered
- Wait 1 second.
- Press the START key
- Pump 4 to 6 litres of air through the sensor

Note: Make sure that the flow sensor is kept still during the pumping operation.

While pumping, the unit records the volume being pumped through the flow sensor and indicates it on the display.

- Press the STOP key when finished pumping.
- Enter the pumped air volume at syringe volume prompt (depending on the size of the calibration pump and times of pumping; i.e. a 2 litre pump pumped 3 times = 6 litres).
- Press ENTER.
- The message "Calibration complete " appears on the display, press the PRINT key to obtain a printout of the calibration report with the following information:



If the message 'EXCESSIVE DEVIATION!` appears on the screen after a calibration, it indicates that the difference between the measured volume and the entered volume is too great (>25%). Check the temperature setting, the syringe volume and the entered syringe volume. If these are all correct change the screen/filter and recalibrate

The test method for the FVC, SVC, MVV and MV test is the same. Proceed as follows:

1. Calibrate the unit

THE UNIT MUST BE CALIBRATED

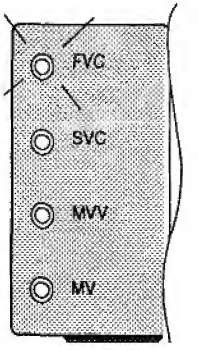
- At the beginning of each day
- If the sensor is changed
- When a significant temperature or pressure difference occurs

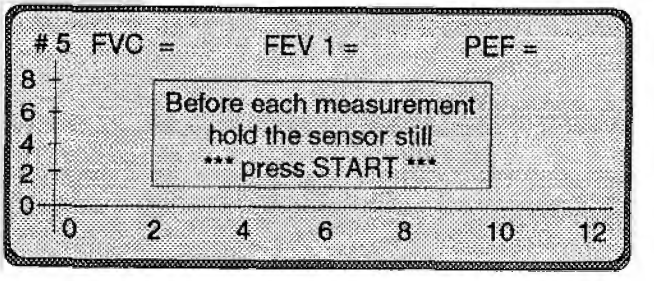
2. Press the function test key

- FVC
- SVC
- MVV
- MV

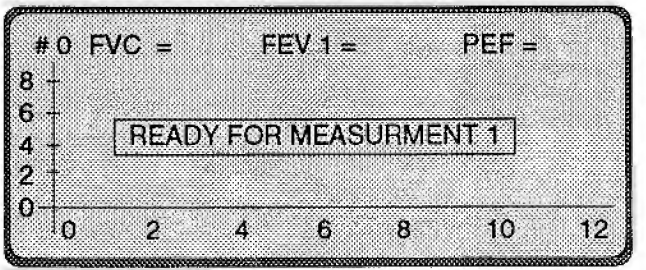
The relevant keyboard lamp lights and the corresponding coordinate presentation appears on the display as shown in this example for FVC

The coordinates represent the graph on which the curve will be drawn with the respiratory volume in litres being represented on the vertical axis and the time in seconds on the horizontal axis.


FVC
SVC
MVV
MV


5 FVC =
FEV 1 =
PEF =
8
6
4
2
0
Before each measurement
hold the sensor still
*** press START ***
0
2
4
6
8
10
12

3. Press the START key



The flow sensor must be held quite still and no air should be breathed into the device for at least one second before and after the START key is pressed.

The message "READY FOR MEASUREMENT" appears on the display together with a volume counter graph for the value. As soon as the patient starts to breathe into the flow sensor, the unit begins to record the expiratory flow. The corresponding curve is represented on the display. The break-off point for the expiration measurement is reached automatically (or the Stop key is pressed).

4. Press the STOP key on completion of the test.

5. Repeat steps 3 and 4 until three measurements have been taken.

Note: If the Start key is again pressed (a fourth or more times), only the best three measurements are stored.

When American standards are stipulated, the message "ATS criteria met" appears on the printout if the deviation (as stipulated by the American Thorasic Society) between the best and second best measurements is not greater than 200ml.

Following a series of patient measurements the best two results are recorded and stored along with the last test made (which may or may not be one of the best three). These three results can then be printed graphical along with a table of the best individual measurements (from these three results). The table of the best measurements can also be displayed on the screen.

Definition of Best

In accordance with the ATS Spirometry Standard (11 November 1994), the best recordings are defined as the highest value from the calculation:

Best = FVC + FEV1

The measurement table (on the printout and on the display) gives the highest individual measurements (e.g. FVC, FEV1, SVC, MVV etc.) from the two best recordings as defined above, and the last recording made. This is true for all parameters except the following which are based solely on the highest FVC + FEV1 value:

- $FEF_{0.2-1.2}$
- $FEF_{25\%-75\%}$
- $FEF_{75\%-85\%}$
- $FEF_{25\%}$
- $FEF_{50\%}$
- $FEF_{75\%}$
- $FIF_{50\%}$

and when loop graph selected:

- ERV
- IRV
- TV

Displaying the Results in Tabular Form

Press the RESULT Key after a measurement, or series of measurements have been made. A measurement table is displayed for the test mode (as indicated by the test lamp) as follows:

FVC

	MEAS	PRED.	%PRED
FVC	4.82	4.31	112
FEV 1.0	4.52	3.50	129
FEV 1/FVC	9.36	8.23	114
FEF.2-1.2			
FEF 25-75%			
FEF 75-85%			

SVC

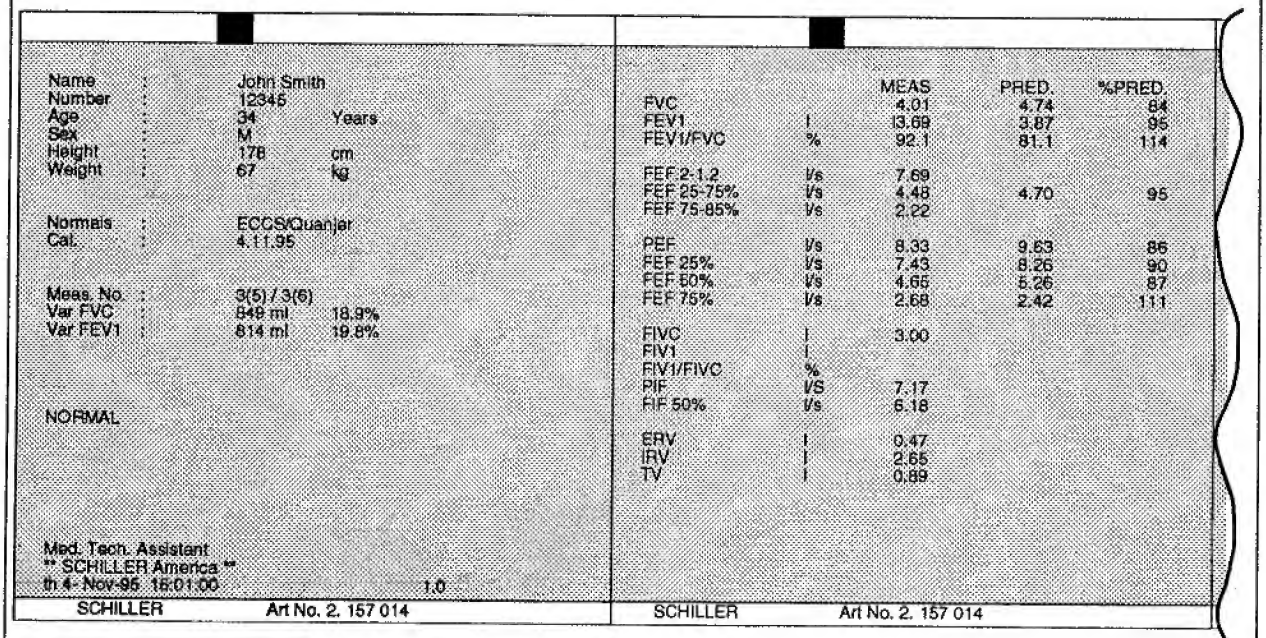
	MEAS	PRED.	%PRED
SVC	-.--	-.--	-.--
ERV	-.--	-.--	-.--
IRV	-.--	-.--	-.--
TV			

MV

	MEAS	PRED.	%PRED
MVV	-.--	-.--	-.--
RR	-.--	-.--	-.--
TV	-.--	-.--	-.--
MV	-.--	-.--	-.--
RR	-.--	-.--	-.--
TV	-.--	-.--	-.--

Obtaining a Printout

Press PRINT after taking all measurements.



Name	:	John Smith
Number	:	12345
Age	:	34 Years
Sex	:	M
Height	:	178 cm
Weight	:	67 kg
Normals	:	ECCS/Quanjer
Cal.	:	4.11.95
Meas. No.	:	3(5) / 3(6)
Var FVC	:	849 ml 18.9%
Var FEV1	:	814 ml 19.8%

NORMAL

Med. Tech. Assistant
** SCHILLER America **
th 4- Nov-95 16:01:00 1.0

SCHILLER Art No. 2. 157 014

		MEAS	PRED.	%PRED.
FVC	l	4.01	4.74	84
FEV1	l	3.69	3.87	95
FEV1/FVC	%	92.1	81.1	114
FEF 2-1.2	l/s	7.69		
FEF 25-75%	l/s	4.48	4.70	95
FEF 75-85%	l/s	2.22		
PEF	l/s	8.33	9.63	86
FEF 25%	l/s	7.43	8.26	90
FEF 50%	l/s	4.65	5.26	87
FEF 75%	l/s	2.68	2.42	111
FIVC	l	3.00		
FIV1	l			
FIV1/FIVC	%			
PIF	l/S	7.17		
FIF 50%	l/s	6.18		
ERV	l	0.47		
IRV	l	2.65		
TV	l	0.89		

SCHILLER Art No. 2. 157 014

The following is given:

- The patient data
- The selected norm values
- The date of last calibration
- The number of tests stored. If more than three tests are made the figure given in brackets indicates the total number of tests carried out. The number of post tests stored, and the total number of post tests made are given in the same manner after the slash. In the example given opposite, a total of 5 tests were carried out and a total of 6 post tests.
- The FVC and FEV1 variation in ml between the best and second best measurements. If this value is within 200ml the message 'ATS criteria met' is printed.
- The diagnostic statement (if enabled in Settings menu)
- The MTA identification
- The user identification
- The date and time of the printout
- The software version and the installed options (M = memory) are also indicated at the bottom of this page.

The second section of the printout comprises:

- the test results presented as a table giving the best values, the predicted values and the best values as a percentage* of the predicted.
- the graph of the best test or the curves for all three tests depending on selection.
- other curves and data dependent on test made

The Graphs of the measurements are given on the subsequent page(s). Note that the FIVC values and the ERV values are only given if Inspiration is taken with the FVC test and when Loop is selected for measurement (see system setup menu page 15).

* *The predicted values (%) given on the printout may differ slightly from the values that would be obtained if manually calculated. The reason is that the measured and predicted values on the printout are rounded to two decimal places, the processor however, uses the actual values - measured to three decimal places - to calculate the % of predicted value. This can account for a possible variation. Where a difference exists, the values given on the printout are always the more accurate.*

Deleting a measurement

The last measurement made can be deleted by pressing DEL

Forced Vital Capacity (FVC) Test

For this test the patient must exhale as quickly as possible from the time of starting the test.

Note: *The FVC test employs the "Back extrapolation" method. If the extrapolated volume is too large (>0.15 litres or 5% of FVC), then a warning appears on the display*

To carry out the test for Forced Vital Capacity (FVC), press key "FVC" and the corresponding coordinate presentation appears on the display

The patient must exhale as quickly as possible from the time of starting the test so be sure that he understands what is required of him. If inspiratory measurements are required, the exhalation can be immediately followed by a maximum inhalation. The inspiration results will be given on the printout.

Before initiating a printout of the FVC Test, ensure that the settings are correct as detailed previously. Press the **PRINT** key to obtain a printout as defined.

Slow Vital Capacity (SVC) Test

The patient should breathe normally 3 times and then inhale maximally to total lung capacity and then expire maximally. Make sure that the patient understands what is required of him.

MVV Test

The patient should breathe as deeply and as rapidly as possible over a period of 6 to 12 seconds so make sure that he understands what is required of him.

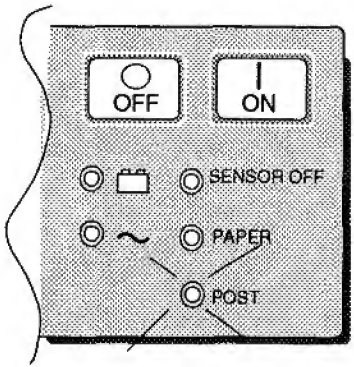
WARNING

EXTREME CARE SHOULD BE EXERCISED WHEN PERFORMING THIS TEST AS THERE IS A DANGER OF HYPERVENTILATION. ENSURE THAT THE PATIENT IS SITTING DOWN.

MV Test

The patient should breathe as normally as possible for up to 60 seconds, but for at least 20 seconds. Make sure that the patient understands what is required of him.

In order to carry out post-medication tests for comparison, press the PRE/POST key and "POST" Lamp lights



The post-medication tests are carried out in the same way as the premedication tests (three measurements stored). The printout following post-medication tests will give the curves of both pre and post-medication tests (the premedication curve is bold). The measurement results are shown as the best results (pre/post), results as a percentage of those predicted, (both pre and post) and the percentage change (i.e. difference) between pre and post-medication results.

The diagnosis resulting from the premedication test is also given on this printout.

FVC	**Forced (expiratory) Vital Capacity.** Volume achieved by the quickest possible exhalation after a maximal inhalation.
$FEV_{0.5/1.0/3.0}$	**Forced expiratory volume.** Lung volume in litres, measured after 0.5, 1.0 or 3 seconds forced expiration.
FEF	**Forced Expiratory Flow Respiratory.** Flow in terms of differing lung volumes measured in litres per second.
$FEF_{25-75\%}$	flow speed of the expired air by 25 to 75% of the forced vital capacity (FVC)
$FEF_{75-85\%}$	flow speed of the expired air by 75 to 85% of the forced vital capacity (FVC)
$FEF_{25\%}$	flow speed of the expired air by 25% of the forced vital capacity (FVC)
$FEF_{50\%}$	flow speed of the expired air by 50% of the forced vital capacity (FVC)
$FEF_{75\%}$	flow speed of the expired air by 75% of the forced vital capacity (FVC)
$FEF_{.2-1.2}$	averaged flow between 0.2 and 1.2 litres of the forced expired vital capacity
PEF	**Peak Expiratory Flow**
MEF	**Maximal Expiratory Flow**

$MEF_{75\%}$	flow speed of the expired air by 25% of the forced vital capacity (FVC)
$MEF_{50\%}$	flow speed of the expired air by 50% of the forced vital capacity (FVC)
$MEF_{25\%}$	flow speed of the expired air by 75% of the forced vital capacity (FVC)
$MEF_{75\%} = FEF_{25\%}$	
$MEF_{50\%} = FEF_{50\%}$	
$MEF_{25\%} = FEF_{75\%}$	
ERV	**Expiratory Reserve Volume.** Possible further expiration starting from the normal expiration level
IRV	**Inspiratory Reserve Volume.** Possible further inspiration starting from the normal inspiration level
TV	**Tidal Volume.** Expirational and inspirational volumes during normal respiration
SVC	**Slow Vital Capacity.** Lung volume measured from a complete expiration following a deep inspiration
MV	**Expired or Minute Ventilation.** Volume of expired air in litres per minute measured over a minimum of one minute

MVV	**Maximum Voluntary Ventilation.** Maximum volume of air which can be moved on expiration while breathing as deeply and as rapidly as possible
RR	**Respiration Rate**
FMFT	**Forced Mid-expiratory Flow Time.** Time difference between the 25% and 75% points of the FVC
FIVC	**Forced Inspiratory Vital Capacity.** Inspiration volume achieved between a maximal expiration and a maximal inspiration
$FIV_{1.0}$	forced inspiratory air volume in litres measured in the first second
$FIV_{1.0}$ / FIVC	forced inspiratory air volume measured in the first second as a percentage of forced inspiratory vital capacity
$FIV_{1.0}$ / FVC	forced inspiratory air volume measured in the first second as a percentage of forced expiratory vital capacity
PIF	**Peak Inspiratory Flow.** Maximum inspiratory flow speed in litres / second
MIF	**Maximum Inspiratory Flow.** Maximum inspiratory flow in litres
$MIF_{50\%}$	flow speed by 50 % of the forced inspiratory vital capacity

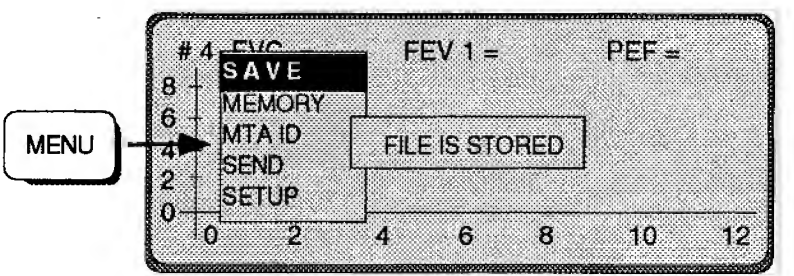
This section is only applicable when the memory option is installed.

Automatic Storage

To store a measurement automatically the save option in the setting menu must be set to AUTO - See page 19. When this is set, the patients measurements are stored automatically at the end of the test (when a new patient is entered).

Manual Storage

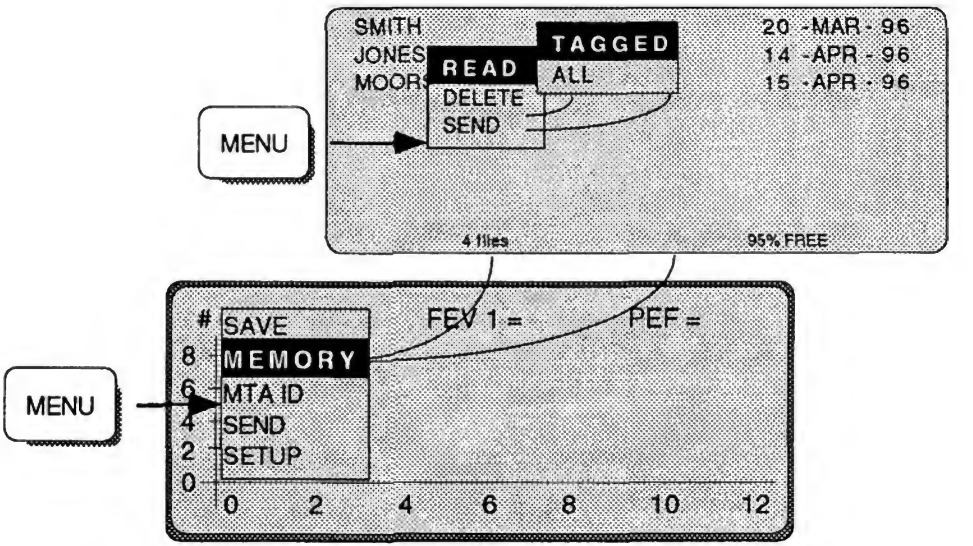
To store a measurement manually press the MENU key, highlight the SAVE option, and press enter. The message FILE IS STORED is displayed. Press ENTER to exit.



The message MEMORY FULL appears when all memory space is used. Old records must be deleted (see next section) to store the current recording. In auto mode this message will appear when a new patient is entered. If you wish to store the current measurement, space must be made available before entering new patient details.

This section is only applicable when the memory option is installed.

Enter the memory screen press the MENU key, highlight the MEMORY option, and press enter. A list of the stored recordings is displayed. At the bottom of the screen the number of files stored is displayed along with the percentage of free memory available. Six files are displayed on each page. Use the up and down cursor keys to select a file. When the bottom or top file is highlighted the next/preceding page, is automatically displayed when the down or up cursor key is again pressed.



With a file highlighted, press the MENU key to display the following options:

Read Highlight this option and press ENTER to display the patient data of the selected file. Obtain a printout of the selected file by pressing the PRINT key. Display results by pressing the RESULT key.

Delete Highlight this option and press ENTER to delete all or selected files. When this option is selected you are prompted by the message TAGGED or ALL. Select the option you require to delete only the tagged files or all stored files.

Send Highlight this option and press ENTER to send all or selected files over the RS-232 interface. When this option is selected you are prompted by the message TAGGED or ALL. Select the option you require to send only the tagged files or all stored files. See the following page for sending procedure.

To cancel any operation in the above option press the MENU key.

Tagging a Stored File (for Deletion or Sending)

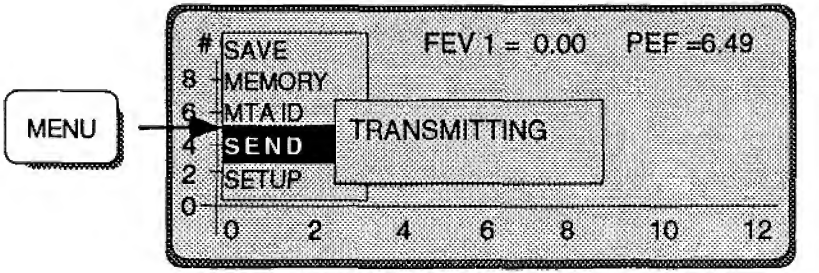
Highlight the File (with the READ/DELETE/SEND menu *NOT* displayed - if the menu is displayed, exit by pressing the MENU key) and press ENTER. An asterisk appears by the side of the file. Cancel the tag by pressing ENTER again.

Exiting the Memory Option

Press any of the Function keys (FVC, SVC, MVV, or MV) to return to the measurement screen. *Note that it is not possible to exit the memory screen when the Delete or Send menu options are selected (Tagged/All displayed); press the MENU key first then and then the function key.*

Measurements can be sent to the SEMA data management system. To send a measurement proceed as follows:

- Connect the PC to the RS-232 connector on the right hand side of the unit
- Carry out the measurement(s) as described previously
- Press the MENU key and select SEND



When the transmission is complete a message is displayed showing that successful transmission has been completed. If an error message is displayed e.g. 'serial link time-out' check settings in the PC and on the unit. Check the cable connection. Ensure that the Baud rate and the parity settings are the same in both the PC and the unit (SETUP menu).

Stored files can also be sent - see previous page.

The casing of the SP-1 should be cleaned with a soft cloth on the surface only. *Disconnect the unit before cleaning.*

WARNING

DO NOT, UNDER ANY CIRCUMSTANCES, IMMERSE THE APPARATUS INTO A CLEANING LIQUID OR STERILIZE WITH HOT WATER, STEAM, OR AIR.

Self-test

At the time of print his function was not fully defined

A table giving information for the service staff is printed out.

Maintenance

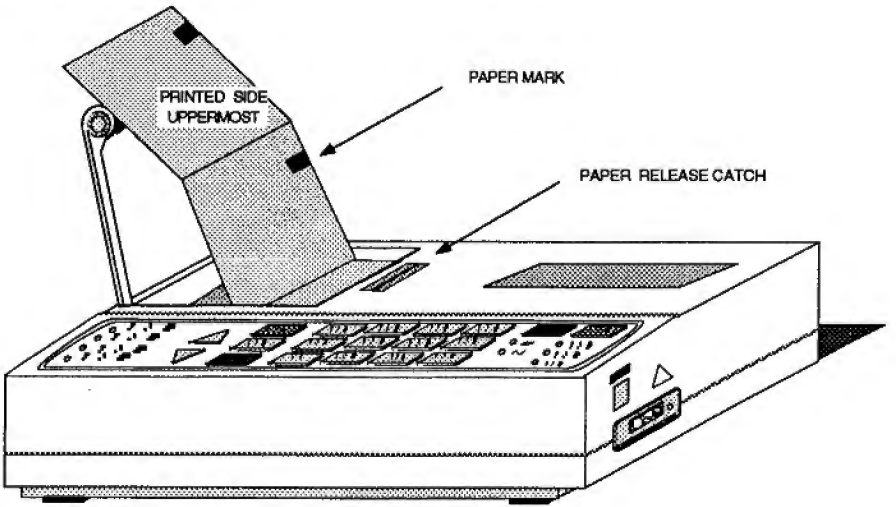
At 12 monthly intervals, the unit should undergo a technical safety check. The extent of this check should include the following:

- Visual inspection of the unit, sensor and cables.
- Electrical safety tests according to IEC 601-1.
- Functional tests according to the Service Handbook.

The test results must be documented.

The recording paper must be replaced as soon as the end of the paper is indicated by a red stripe on the lower edge. After the indication first appears, there are about 8 pages left. However, we recommend that the paper be replaced immediately.

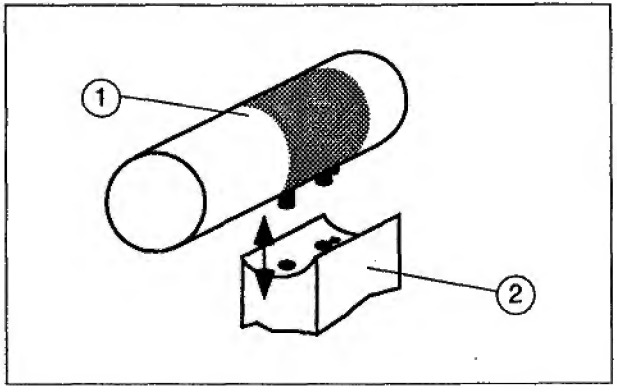
If no paper is left, the printing process is interrupted and the paper warning lamp starts to blink.



- Push paper compartment release and lift up cover.
- Remove the remaining paper.
- Place a new paper pack into the drawer.
- Check that the printed (grid) side is facing upwards, and place the beginning of the paper over the guide roller.
- Close lid and press firmly until release catches.
- Press **STOP** to transport the paper to the start position.

NOTE: *WELCH ALLYN SCHILLER can only guarantee an excellent printout if WELCH ALLYN SCHILLER original chart paper or a chart paper of the same quality is used.*

Flow Sensor SP-150



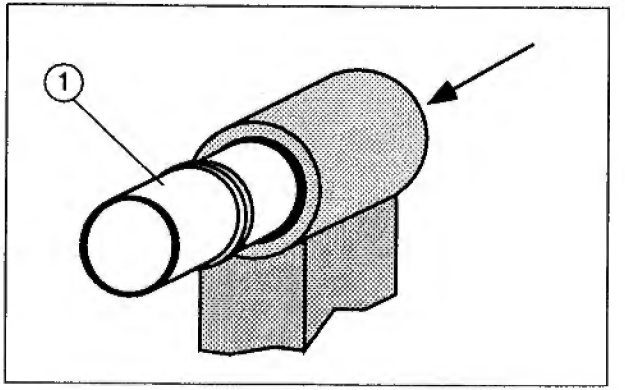
1. Remove disposable mouthpiece (1) by gently but firmly pulling it away from the handle (2).

2. Discard the complete assembly.

3. Position new disposable mouthpiece **(Part No. 2.100077)** and gently but firmly click it in position.

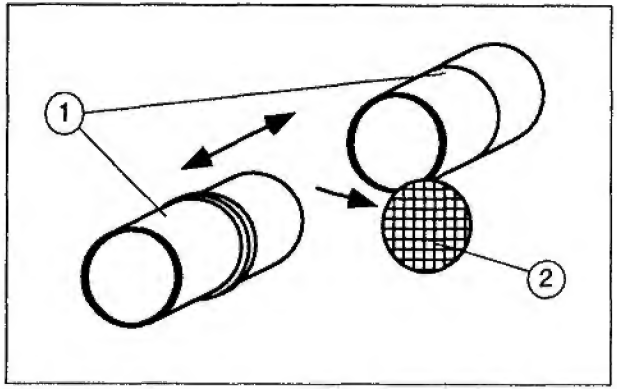
NOTE: The disposable mouthpiece can only be positioned in one direction and no force is necessary to insert it on the handle.

Flow Sensor SP-20



1. Slide out the combined filter/mouthpiece assembly (1). This is only possible in one direction.

2. Unscrew the assembly.



3. Remove and discard filter (2).

4. Clean and disinfect the assembly after every patient.

5. Insert a new filter **(Part No. 2.100123)**.

6. Carefully screw the two halves of the assembly together again. *Make sure that the filter is not displaced.*

7. Push the combined filter/mouthpiece assembly gently but firmly into the outer tube until it makes contact on the outside edge of the outer tube. The assembly can only go in one direction.

The diagnostic interpretation is dependent upon the country. The factors used in the evaluation for diagnosis are automatically included in the respective language software and described in the following chapters.

Diagnosis Setting `International`

Note: *When `International` is set, diagnostic norms are predicted using the VC value (if taken). If VC values are not recorded, FVC is used. That is:*

- *%VC = 100 * VC/VC predicted (when VC measurement taken), otherwise 100 * FVC/FVC predicted*

- *FEV% = 100 * FEV1/VC (when VC measurement taken), otherwise 100 * FEV1/FVC*

Possible respiratory problems are diagnosed on evaluation of the following factors:

Diagnosis	%VC (FVC)	FEV1%
Normal Condition	>80%	>70%
Restrictive	<80%	-
Obstructive	-	<70%
Combined	<80%	<70%

The measurement FEV1/FVC or FEV1/VC will adapted on the screen and on the printout .

Diagnosis Setting `American`

For the USA and Canada, diagnosis of possible respiratory problems is based on the ITS interpretation standard which uses the LLN (Lower Limits of Normal) calculations. These calculations apply to patients between the ages of 5 and 85. The LLN FEV1% value is calculated as follows:

	Male		Female	
Adult	>26 yrs:	Predicted FEV1% -9.2	>21 yrs:	Predicted FEV1% -11.1
Adolescent	19 to 25 yrs:	Predicted FEV1% x 0.848	19 to 20 yrs:	Predicted FEV1% x 0.805
Child	<18 yrs:	Predicted FEV1% x 0.826	<18 yrs:	Predicted FEV1% x 0.791

Using this LLN value, the diagnostic statements and their criteria are as follows:

Diagnosis	Criteria
Normal limits	FEV1/FVC% predicted is >80%
Borderline Obstruction	FEV1/FVC% is 80 to 100% of LLN
Mild Obstruction	FEV1/FVC% is 60 to 80% of LLN
Moderate Obstruction	FEV1/FVC% is 40 to 60% of LLN
Severe Obstruction	FEV1/FVC% is <40% of LLN
Mild Restriction	%FVCpredicted is 60 to 80%
Moderate Restriction	%FVCpredicted is 50 to 60%
Severe Restriction	%FVCpredicted is <50%

The norm values used for the calculation of predicted values are dependent upon the country.

- For Great Britain, Italy, Spain and Switzerland, the ECCS and Quanjer standards are used.
- For Sweden, the Swedish (Berglund) and Quanjer standards are used.
- In Finland the Finnish and Quanjer standards are used.
- In Austria the Austrian standards are used.
- In India the Indian norm values are used.
- In America and Canada the norm values that are used are Knudson, Knudson76, Crapo, Morris, Composite and Polgar. The American norm values are extended with values taken from the ITS (Intermountain Thoracic Society) recommendations.

The factors used in the evaluation for diagnosis and the specific norm values are included in the software and are described in the following pages.

IMPORTANT

DUE TO GREAT DIFFERENCES IN THE SIZE OF THE LUNGS OF CHILDREN, THERE ARE NO STANDARD VALUES FOR CHILDREN UNDER 6 YEARS OF AGE.

Norm Values for Countries Outside the USA

ECCS Values

The safety standards of the European Coal and Steel Community Standards (ECCS) are valid for adults of at least 25 years of age. Patients between the ages of 18 and 25 are calculated on the basis of a 25 year old. The calculation equations are as follows:

	Males	Females
SVC	6.103 x H -0.028 x A -4.654	4.664 x H -0.024 x A -3.284
FVC	5.757 x H -0.026 x A -4.345	4.426 x H -0.026 x A -2.887
FEV1	4.301 x H -0.029 x A -2.492	3.953 x H -0.025 x A -2.604
FEV1/SVC	-0.179 x A +87.21	-0.192 x A +89.10
MEF	1.944 x H -0.043 x A +2.699	1.252 x H -0.034 x A +2.924
PEF	6.146 x H -0.043 x A +0.154	5.50 x H -0.030 x A -1.106
MEF75	5.459 x H -0.029 x A -0.470	3.218 x H -0.025 x A +1.596
MEF50	3.794 x H -0.031 x A -0.352	2.450 x H -0.025 x A +1.156
MEF25	2.605 x H -0.026 x A -1.336	1.050 x H -0.025 x A +1.107

H: Height in meters A: Age

Quanjer & Tammeling Comparisons

The Quanjer and Tammeling comparison is valid for children between the ages of 6 and 17 as follows:

	Boys	Girls
SVC = FVC	1.00 x H(power 2.7)	0.95 x H(power 2.7)
FEV1	0.84 x H(power 2.7)	0.81 x H(power 2.7)
FEV1/SVC	0.84	0.84
MEF = PEF	8.2 x H -6.8	6.6 x H -5.3
MEF50	5.6 x H -4.4	4.6 x H -3.3

H: Height in meters

Austrian Standard Values (Österreich)

BOYS 5 - 17.99 years (1.09 - 1.96m)	MALES 18 - 90 years (1.44 - 2.00m)
ln(FVC) = -1.142 + 1.259H + 0.004070A √W	FVC = -11.606 + 8.172H - 0.0339A x H + 1.2869ln(A)
ln(FEV1) = -1.178 + 1.221H + 0.003841A √W	FVC1 = -8.125 + 6.212H - 0.0300A x H + 0.9770ln(A)
ln(PEF) = -0.214 + 0.921H + 0.0467A + 0.0020W	√PEF = 1.798 + 2.311ln(H) + 0.0159A - 0.000248A(power 2)
ln(PEF75) = -0.077 + 0.770H + 0.0373A + 0.0025W	√PEF75 = 1.581 + 1.854ln(H) + 0.0213A - 0.000283A(power 2)
ln(PEF50) = -0.522 + 0.843H + 0.0300A + 0.0035W	√PEF50 = 1.490 + 1.290ln(H) + 0.0125A - 0.000218A(power 2)
ln(PEF25) = -1.576 + 1.166H + 0.0219A + 0.0021W	√PEF25 = 1.314 + 0.898ln(H) - 0.0083A - 0.000026A(power 2)
FEV1 %FVC = 101.99 - 1.191H(power 2) - 3.962ln(A)	FEV1 %FVC = 101.99 - 1.191H(power 2) - 3.962ln(A)
GIRLS 5 - 15.99 years (1.10 - 1.82m)	**FEMALES 16 - 90 years (1.40 - 1.90m)**
ln(FVC) = -3.842 + 4.1632√H + 0.1341√A - 1.614Fi	FVC = -10.815 + 6.640H - 0.0408A x H + 1.7293ln(A)
ln(FEV1) = -3.877 + 3.9809√H + 0.1485√A - 1.322Fi	FVC1 = -6.995 + 5.174H - 0.0314A x H + 1.0251ln(A)
ln(PEF) = 0.411 + 1.793ln(H) + 0.4251ln(A) - 0.910Fi	√PEF = 1.832 + 1.838ln(H) + 0.0078A - 0.000172A(power 2)
ln(MEF75) = 0.455 + 1.616ln(H) + 0.3738ln(A) - 0.861Fi	√PEF75 = 1.779 + 1.421ln(H) + 0.0096A - 0.000179A(power 2)
ln(MEF50) = 0.256 + 1.643ln(H) + 0.3481ln(A) - 1.089Fi	√PEF50 = 1.561 + 1.177ln(H) + 0.0045A - 0.000140A(power 2)
ln(MEF25) = -0.772 + 2.002ln(H) + 0.3063ln(A) - 0.409Fi	√PEF25 = 1.372 + 0.938ln(H) - 0.0152A + 0.000036A(power 2)
FEV1 %FVC = Mw = 92.33	FEV1 %FVC = 118.993 - 3.0320H(power 2) - 6.9053ln(A)

H = Height in meters, A = Age in years, W = Weight in kg, Fi = Body fat index = $H/\sqrt[3]{W}$

Swedish Standards (Berglund)

The Swedish (Berglund) standard is valid for adults between the ages of 18 and 75 years as follows:

	Males	Females
FEV%	91.79 -(0.373 x A)	92.11 -(0.261 x A)
SVC	1.09 [(4.81 x H) -(0.020 x A) -2.81]	1.09 [(4.04 x H) -(0.022 x A) -2.35]
FEV	1.01.09 [(3.44 x H) -(0.033 x A) -1.00]	1.09 [(2.67 x H) -(0.027 x A) -0.54]

A: Age H: Height in meters

Finnish Standards

The Finnish standard is valid for adults from the age of 18 years as follows:

Males	
SVC (l)	exp [(-0.00833 x A) + (0.6309 x log A) + (-1.4750 / H) + 0.9047]
FEV1 (l)	exp [(-0.00587 x A) + (0.2756 x log A) + (-1.1655 / H) + 1.0980]
FVC (l)	exp [(-0.00827 x A) + (0.5860 x log A) + (-1.4468 / H) + 0.9461]
FEV1 / SVC (%)	exp [(0.00246 x A) + (-0.3553 x log A) + (0.3095 / H) + 2.1933]
FEV1 / FVC (%)	exp [(0.00240 x A) + (-0.3104 x log A) + (0.2813 / H) + 2.1519]
PEF (l/s)	exp [(-0.00211 x A) + (0.1049 x log A) + (-0.6774 / H) + 1.3255]
Females	
SVC (l)	exp [(-0.01016 x A) + (0.6995 x log A) + (-1.4518 / H) + 0.7763]
FEV1 (l)	exp [(-0.00920 x A) + (0.4772 x log A) + (-1.3284 / H) + 0.9296]
FVC (l)	exp [(-0.00982 x A) + (0.6358 x log A) + (-1.4137 / H) + 0.8320]
FEV1 / SVC (%)	exp [(0.00096 x A) + (-0.2223 x log A) + (0.1233 / H) + 2.1533]
FEV1 / FVC (%)	exp [(0.00062 x A) + (-0.1586 x log A) + (0.0853 / H) + 2.0975]
PEF (l/s)	exp [(-0.00677 x A) + (0.4017 x log A) + (-0.7422 / H) + 0.9661]

A: Age H: Height in meters log: Logarithm to base 10

Indian Equations

The Indian equations are valid for patients from the age of 7 years as follows:

	Males	Females
	<30 years old:	
FVC	0.055 x H + 0.019 x A -6.058	0.030 x H + 0.006 x A - 2.284
FEV1	0.039 x H - 0.010 x A -3.266	0.025 x H - 0.011 x A - 1.424
	>30 years old:	
FVC	0.054 x H - 0.018 x A -4.832	0.043 x H - 0.010 x A - 3.755
FEV1/FVC	-0.1756 x H - 0.2457 x A -119.346	-0.0334 x H - 0.2146 x A - 94.8867
SVC	0.0522 x H - 0.0114 x A -4.859	0.0587 x H - 0.0296 x A - 5.927
FEV3	0.0485 x H - 0.0183 x A -4.138	0.0533 x H - 0.0105 x A - 5.660
FEF25-75%	0.0173 x H - 0.0407 x A -1.6108	0.0245 x H - 0.0336 x A - 0.1399
PEF	0.0850 x H - 0.0187 x A -6.2083	0.0497 x H - 0.0018 x A - 2.7154
FEF50	0.0195 x H - 0.0365 x A -1.7383	0.0272 x H - 0.0279 x A - 0.2704
FEF75	0.0088 x H - 0.0301 x A -1.0402	0.0113 x H - 0.0288 x A - 0.5012
MVV	1.3056 x H - 0.5228 x A -93.2102	0.7149 x H - 0.3624 x A - 25.0208

A: Age, H: Height in meters

Norm Values for USA and Canada

Morris Norm Values

The Morris equations are valid for women between 56 and 72 inches tall and within the age range of 20 to 90 years, and for men between 58 and 80 inches tall and within the age range of 20 to 90 years as follows:

	Males	Females
FVC	0.1480 x H -0.0250 x A -4.241	0.1150 x H -0.0240 x A -2.852
FEV1	0.0920 x H -0.0320 x A -1.260	0.0890 x H -0.0250 x A -1.932
FEV1/FVC	-0.3118 x H -0.2422 x A +107.120	-0.0679 x H -0.1815 xA +88.700
FEF0.2 - 1.2	0.1090 x H -0.0470 x A +2.010	0.1450 x H -0.0360 x A -2.532
FEF25 - 75	0.0470 x H -0.0450 x A +2.513	0.0600 x H -0.0300 x A +0.551
FEF75 - 85	0.0130 x H -0.0230 x A +1.210	0.0250 x H -0.0210 x A +0.321

The Morris normals are extended with the following:

	Males	Females
FEV0.5	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV3.0	-0.1359 x H -0.0271 x A -3.512	-0.1123 x H -0.0257 x A -2.745
FEV3.0/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160
MVV	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

Crapo Norm Values

The Crapo equations are valid for men between 61 and 77 inches tall and within the age range of 18 to 89 years, and for women between 57 and 71 inches tall and within the age range of 18 to 89 years as follows:

	Males	Females
FVC	0.1524 x H -0.0214 x A -4.650	0.1247 x H -0.0216 x A -3.590
FEV1	0.1052 x H -0.0244 x A -2.190	0.0869 x H -0.0255 x A -1.578
FEV3	0.1359 x H -0.0271 x A -3.512	0.1123 x H -0.0257 x A -2.745
FEV1/FVC	-0.3302 x H -0.1520 x A +110.490	-0.5131 x H -0.2520 xA +126.580
FEF25 - 75	0.0518 x H -0.0380 x A +2.133	0.0391 x H -0.0460 x A +2.683
MVV Vol.	3.4040 x H -1.2600 x A -21.400	2.0500 x H -0.5700 x A -5.500

The Crapo normals are extended with the following ITS equations:

	Males	Females
FEV0.5	0.0831 x H -0.0152 x A -1.914	0.0605 x H -0.0185 x A -0.809
FEV3.0/FVC	-0.1593 x H -0.1450 x A +112.090	-0.2380 x H -0.1630 x A +118.160

A: Age H: Height in inches

Knudson Norm Values

The Knudson equations are valid for both children and adults in specific groups according to age and height as shown following:

	Males	Females
	H = 44 to 61 inches, A = 6 to 11 yrs	*H = 42 to 58 inches, A = 6 to 10 yrs*
FVC	0.1039 x H + 0.0 x A -3.376	0.1092 x H + 0.0 x A -3.749
FVC0.5	0.0760 x H +0.0430 x A -3.050	0.0480 x H + 0.0610 x A -1.740
FEV1	0.0884 x H + 0.0 x A - 2.914	0.0853 x H + 0.0 x A - 2.758
FEV1/FVC	-0.2065 x H + 0.0 x A + 100.439	-0.4849 x H + 0.6655 x A + 109.974
FEF25 - 75	0.0859 x H + 0.0 x A - 2.320	0.0559 x H + 0.0 x A - 0.812
PEF	0.1980 x H + 0.1660 x A - 8.061	0.1240 x H + 0.1570 x A - 3.920
FEF50	0.0960 x H + 0.0 x A - 2.545	0.0 x H + 0.1846 x A + 0.736
FEF75	0.0434 x H + 0.0 x A - 1.015	0.0277 x H + 0.0 x A - 0.166
MVV	3.0300 x H - 0.8160 x A - 37.900	2.7600 x H + 3.4000 x A - 108.120
	H = 55 to 76 inches, A = 12 to 25 yrs	*H = 52 to 72 inches, A = 11 to 20 yrs*
FVC	0.1499 x H + 0.0739 x A - 6.887	0.1057 x H + 0.0699 x A - 4.447
FVC0.5	0.0760 x H + 0.0430 x A - 3.050	0.0480 x H + 0.0610 x A - 1.740
FEV1	0.1318 x H + 0.0636 x A - 6.118	0.0892 x H + 0.0694 x A - 3.762
FEV1/FVC	-0.2065 x H + 0.0 x A + 100.439	-0.4849 x H + 0.6655 x A + 109.974
FEF25 - 75	0.1369 x H + 0.0749 x A - 6.199	0.0709 x H + 0.1275 x A - 2.801
PEF	0.1980 x H + 0.1660 x A - 8.061	0.1240 x H + 0.1570 x A - 3.920
FEF50	0.1379 x H + 0.1150 x A - 6.385	0.0732 x H + 0.1111 x A - 2.304
FEF75	0.1008 x H - 0.0057 x A - 4.242	
MVV	4.6800 x H + 1.8000 x A - 192.320	2.7600 x H + 3.4000 x A - 108.12
For patients over 18 yrs, the following ITS equitations apply:		
FEV3.0	0.1359 x H - 0.0271 x A - 3.512	0.1123 x H - 0.0257 x A - 2.745
FEV3.0/FVC	-0.1593 x H - 0.1450 x A + 112.090	-0.2380 x H - 0.1630 x A + 118.160
	H = 62 to 77 inches, A = 26 to 120 yrs	*H = 58 to 71 inches, A = 21 to 120 yrs*
FVC	0.1524 x H - 0.0214 x A - 4.650	0.1247 x H - 0.0216 x A - 3.590
FVC0.5	0.0831 x H - 0.0152 x A - 1.914	0.0605 x H - 0.0185 x A - 0.809
FEV1	0.1052 x H - 0.0244 x A - 2.190	0.0869 x H - 0.0255 x A - 1.578
FEV3.0	0.1359 x H - 0.0271 x A - 3.512	0.1067 x H - 0.0257 x A - 2.745
FEV1/FVC	0.0 x H - 0.1050 x A + 86.686	-0.4704 x H - 0.1896 x A + 121.678
FEF0.2 - 1.2	0.1090 x H - 0.0470 x A + 2.010	0.1450 x H - 0.0360 x A - 2.532
FEF25 - 75	0.1471 x H - 0.0363 x A - 4.518	0.0531 x H - 0.0344 x A + 1.128
FEF75 - 85	0.0130 x H - 0.0230 x A + 1.210	0.0250 x H - 0.0210 x A + 0.321
PEF	0.2390 x H - 0.0350 x A - 5.990	0.1240 x H - 0.0250 x A - 0.740
FEF25	0.0900 x H - 0.0200 x A + 2.726	0.0690 x H - 0.0190 x A + 2.147
FEF50	0.1737 x H - 0.0366 x A - 5.409	0.0681 x H - 0.0289 x A + 0.609
FEF75	0.0787 x H - 0.0230 x A - 2.483	0.0244 x H - 0.0259 x A + 1.118
MVV	3.0300 x H - 0.8160 x A - 37.900	2.1400 x H - 0.6850 x A - 4.870
In addition, there are the following ITS equations:		
FEV3.0/FVC	-0.1593 x H - 0.1450 x A + 112.090	-0.2380 x H - 0.1630 x A + 118.160

Knudson 76 Norm Values

The Knudson 76 equations are valid for both males and females in specific age groups as follows:

	Males	Females
	Age <25 yrs	*Age <20 yrs*
FVC	0.1270 x H + 0.078 x A -5.508	0.0838 x H + 0.092 x A -3.469
FVC0.5	0.0762 x H +0.043 x A -3.054	0.0483 x H + 0.061 x A -1.738
FEV1.0	0.1168 x H + 0.045 x A - 4.808	0.0686 x H + 0.085 x A - 2.703
FEV3.0	0.1321 x H + 0.066 x A - 5.531	0.0838 x H + 0.086 x A - 3.417
FEV1/FVC	-0.2210 x H - 0.140 x A + 103.64	-0.2819 x H - 0.109 x A + 107.38
FEF25 - 75	0.1499 x H + 0.0 x A - 5.443	0.0635 x H + 0.121 x A - 0.893
PEF	0.1981 x H + 0.166 x A - 8.060	0.1245 x H + 0.157 x A - 3.916
FEF25	0.1778 x H + 0.147 x A - 7.054	0.1118 x H + 0.144 x A + 3.365
FEF50	0.1295 x H + 0.081 x A - 4.975	0.0864 x H + 0.120 x A + 2.531
FEF75	0.0813 x H + 0.0 x A - 2.455	0.0 x H + 0.139 x A - 0.692
	Age ≥25 yrs	*Age ≥20 yrs*
FVC	0.1651 x H - 0.029 x A - 5.459	0.0940 x H - 0.022 x A - 1.774
FVC0.5	0.0940 x H - 0.017 x A - 2.746	0.0483 x H - 0.014 x A - 0.406
FEV1.0	0.1321 x H - 0.027 x A - 4.203	0.0686 x H - 0.021 x A - 0.794
FEV3.0	0.1600 x H - 0.031 x A - 5.245	0.0889 x H - 0.023 x A - 1.633
FEV1/FVC	-0.2210 x H - 0.140 x A + 103.64	-0.2819 x H - 0.109 x A + 107.38
FEF25 - 75	0.1143 x H - 0.031 x A - 1.864	0.0533 x H - 0.024 x A - 1.171
PEF	0.2388 x H - 0.035 x A - 5.993	0.1245 x H - 0.025 x A - 0.735
FEF25	0.2235 x H - 0.035 x A - 5.618	0.1092 x H - 0.025 x A + 0.132
FEF50	0.1753 x H - 0.015 x A - 5.400	0.0889 x H - 0.013 x A - 0.444
FEF75	0.1118 x H - 0.012 x A - 4.143	0.0 x H - 0.014 x A - 3.042

A: Age H: Height in inches

Composite Norm Values

Selection of the Composite normals provides selected equations taken from other tables as follows:

Value	Equation Reference
FVC	Knudson
FEV1	Knudson
FEV3	Crapo
FEF25 - 75	Knudson
FEF75 - 85	Morris
FEF0.2 - 1.2	Morris
MVV	Crapo
SVC	Knudson (same as FVC)

Polgar Norm Values

The Polgar equations are valid for both children and adults in specific groups according to age as follows:

	Males	Females
	Age under 18 years	*Age under 18 years*
FVC	H(power 3)*0.0000071 +H(power 2) *0.00057 -H*0.0123 +0.14	H(power 3)*0.0000076 +H(power 2) *0.00048 +H*0.0112 +0.13
FVC0.5	H*0.076 +A*0.043 -3.05	-
FEV1.0	H(power 3)*0.00000087 +H*0.00035 -H*0.0086 +0.1	H(power 3)*0.0000086 +H(power 2) *0.00035 -H*0.0086 +0.1
FEF25 - 75%	H*0.1109 -3.46	H*0.1109 -3.46
PEF	H*0.2219 -7.09	H*0.2219 -7.09
MVV	H*4.68 -A*1.8 -192.32	H*2.76 -A*3.4 -108.12
	Age 18 to 25 years	*Age 18 to 20 years*
FVC	H*0.1499 +A*0.0739 -6.887	H*0.1057 +A*0.0699 -4.447
FVC0.5	H*0.0760 +A*0.0430 -3.050	H*0.0480 +A*0.00610 -1.740
FEV1.0	H*0.1318 +A*0.0636 -6.118	H*0.0892 +A*0.0694 -3.762
FEF25 - 75	H*0.1369 +A*0.0749 -6.199	H*0.0709 +A*0.1275 -2.801
PEF	H*0.1980 +A*0.1660 -8.061	H*0.1240 +A*0.1570 -3.920
FEF50	H*0.1379 +A*0.1150 -6.385	H*0.0732 +A*0.1111 -2.304
FEF75	H*0.1008 -A*0.0057 -4.242	H*0.0617 +A*0.2923 -4.401
MVV	H*4.68 +A*1.8 -192.32	H*2.76 +A*3.4 -108.12
	Age over 26 years	*Age over 20 years*
FEF3.0	-	H*0.1067 -A*0.0257 -2.745
FEF0.2-1.2	H*0.1090 -A*0.0470 +2.010	H*0.1450 -A*0.0360 -2.532
FEF25 - 75%	H*0.1471 -A*0.0363 -4.518	H*0.0531 -A*0.0344 +1.128
FEF75 - 85%	H*0.0130 -A*0.0230 +1.210	H*0.0250 -A*0.0210 +0.321
PEF	H*0.2390 -A*0.0350 -5.990	H*0.1240 -A*0.0250 -0.740
FEF25	H*0.0900 -A*0.0220 +2.726	H*0.0690 -A*0.0190 +2.147
FEF50	H*0.1737 -A*0.0366 -5.409	H*0.0681 -A*0.0289 +0.609
FEF75	H*0.0787 -A*0.0230 -2.483	H*0.0244 -A*0.0259 +1.118
MVV	H*3.03 -A*0.816 -37.9	H*2.14 -A*0.685 -4.87

A: Age H: Height in inches, The remaining values are taken from the ITS equations.

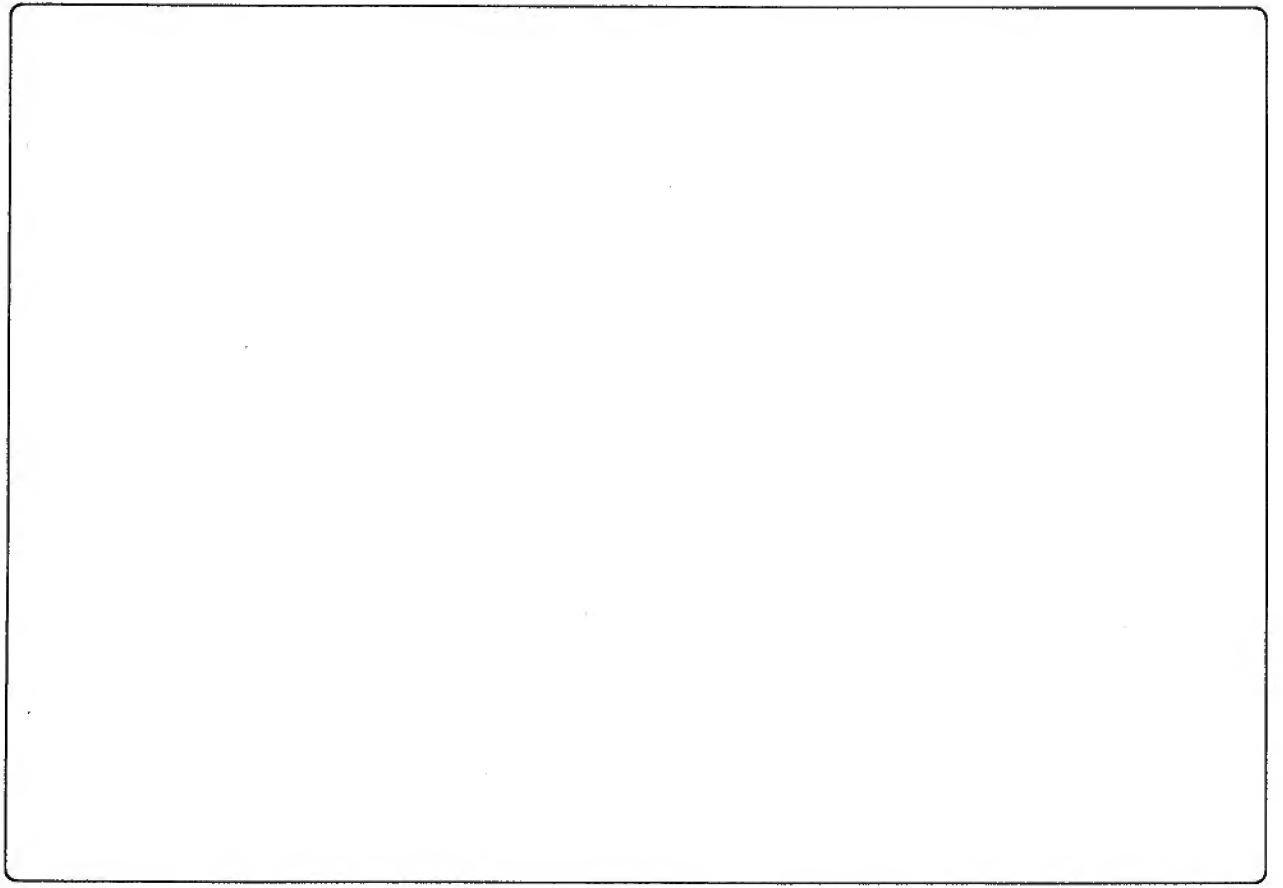
Technical data subject to change without notice.

Safety standard:	BF according to IEC and complying with the following:
	RL 93/42/EEC
	EN 60601-1:1990
	IEC 601-1
	pr EN 1441:1994
	IEC 513:1994
Protection class:	I according to IEC, VDE, SEV
	IIa according to RL 93/42/EEC
Dimensions (l/w/h):	290 x 210 x 69 mm: 11.4 x 8.3 x 2.7 ins
Weight:	2.9 kg: 6.3lbs
Mains Supply:	100 to 115 / 220 to 240 VAC, 50/60 Hz
LCD	Liquid crystal, display for graphic and alpha numeric representation
	Resolution - 192 x 64 dots variable contrast

Battery:	Built-in 12 V lead-acid battery (rechargeable).
	Normal working time - 5 hours
	Charging time - 15 hours for a completely discharged battery (<6 hours to 90%)
Power Consumption:	28 VA max.
Control Panel:	Splashproof Rubber keys
Storage:	Memory for approximately 50 measurements
Paper Speed:	25 mm/s
Chart Paper:	Thermoreactive Z-folded, 90 mm wide, perforation 90mm (3.54 ins)
Printing Process:	High-resolution thermal print head

Method of Measurement:	Pneumotachometer
Measurement Ranges:	Flow: 0 to ±14 l/s; Volume: 0 to ±11 litres
Measurement Accuracy:	±2%
Flow Impedance:	Less than 0.2 mbar • s/l at 12 l/s
Measured Values:	FVC, ERV, IRV, TV, FVC, $FEV_{0.5}$, $FEV_{1.0}$, $FEV_{3.0}$, $FEV_{0.5}$/SVC, $FEV_{1.0}$/FVC, $FEV_{3.0}$/VC, $FEF_{0.2-1.2}$ (litres), $FEF_{25-75\%}$, $FEF_{75-85\%}$, PEF, $MEF_{75\%}$, $MEF_{50\%}$, $MEF_{25\%}$, MV, MVV, FIVC, $FIV_{1.0}$, $FIV_{1.0}$/FIVC, $FIV_{1.0}$/FVC, PIF, $MIF_{50\%}$.
	Comparison pre/post medication possible.
	Extrapolated predicted values
Prediction Equation:	Adults: ECCS / Austria / Berglund / Finnish / Indian / Morris / Crapo / Knudson / Knudson 76 / Polgar / Composite
	Children: Quanjer & Tammeling / Austria / Indian / Knudson / Knudson 76 / Polgar
Standards Compliance:	ATS, OSHA, NIOSH

Environmental Conditions:	Temperature, Operating:	10° to 40° C
	Temperature, Storage:	-10° to 55° C
	Relative humidity:	25 to 95% (non condensing)
	Atmospheric pressure:	700 to 1060 hPa
RS-232 (V24) Interface	**Protocol:**	Asynchronous
	Baud Rate:	300 to 38400 Baud
	Byte Format:	1 start bit, 8 data bits 0 or 1 parity bit (+ or -), 1 stop bit
	Transfer Control:	By means of CTS, RTS
	Connection Socket:	3 x D subminiature (9 pole female), wired as DTE (Data Terminal Equipment).
Pin Connections:	Pin 3 TXD1 O	(output data)
	Pin 2 RXD1 I	(input data)
	Pin 7 RTS1 O	(request for output)
	Pin 8 CTS1 I	(ready for output)
	Pin 5 GND	(ground)



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